

IRB: G  
 Protocol #: 2233  
 Date: 1/27/05  
 Reviewer: Dr. Lipman

## Additional DHHS protections Pertaining to Biomedical & Behavioral Research Involving Prisoners as Subjects

The purpose of this checklist is to aid you in your evaluation of CDC research involving prisoners. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. These requirements are in addition to those imposed under other subparts of the Federal regulation.

On June 20, 2004, the Secretary of the Department of Health and Human Services (DHHS) authorized waiver of the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2), to allow DHHS to conduct or support certain important and necessary epidemiologic research on prisoners. Epidemiologic studies that meet the following criteria would qualify for the waiver:

- The sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and
- Where the institution responsible for the conduct of the research certifies to OHRP that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a) (3)-(7) and determined and documented that
  - The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
  - Prisoners are not a particular focus of the research.

If the IRB determines that the study qualifies for this waiver, the IRB Administrator will send the notification to OHRP.

### Minimal Risk

The Federal regulations divide research into that which is minimal or not greater than minimal risk to the participant & that which is greater than minimal risk. The definition of minimal risk for research involving prisoners is given in §46.303(d), which reads as follows:

Minimal risk is the *probability & magnitude* of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of health persons.

**Level of Risk for this protocol (please insert minimal or greater than minimal):**

***An IRB can only approve research that falls into one of the following four categories (complete/check one only):***

Category	45 CFR 46 Subpart C §46.306	Notes
<i>Cause &amp; Effect</i>	study of the possible causes, effects, & processes of incarceration, & of criminal behavior, provided...	
	...that the study presents no more than minimal risk AND	
	no more than inconvenience to the subjects.	
<i>Institutional Structures</i>	study of prisons as institutional structures or of prisoners as incarcerated persons, provided...	
	...that the study presents no more than minimal risk AND	

Category	45 CFR 46 Subpart C §46.306	Notes
	no more than inconvenience to the subjects.	
<i>Conditions Affecting Prisoners as Class</i>	research on conditions particularly affecting prisoners as a class (e.g., vaccine trials ...on hepatitis which is much more prevalent in prisons; & research on social & psychological problems such as alcoholism, drug addition, & sexual assaults)...	
<i>Improving Health &amp; Well-being</i>	research on practices, both innovative & accepted, which have the intent & reasonable probability of improving the health or well-being of the subject.	

Please use the following determination key when evaluating research involving prisoners to ensure that the **additional safeguard** has been satisfactorily addressed:

**Y** = adequately addressed in protocol

**P** = problematic

**M** = missing

**N/A** = not applicable

**I** = incomplete

Additional Safeguard	§46.305	Notes
<i>Legal</i>	research...limited by applicable State or local law.	
<i>Controls (a)(1)</i>	Unless the PI provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed...	
<i>Advantages (a)(2)</i>	any possible advantages accruing to the prisoner through his or her participation..., when compared to the general living conditions, medical care, quality of food, amenities & opportunity for earnings in prison, are not of such a magnitude that his or her ability to weigh the risks...against the value of such advantages in the limited choice environment of the prison is impaired;	
<i>Risks (a)(3)</i>	...are commensurate with risks that would be accepted by nonprisoner volunteers;	
<i>Selection (a)(4)</i>	procedures...are fair to all prisoners & immune from arbitrary intervention by prison authorities or prisoners.	
<i>Comprehension (a)(5)</i>	...information is presented in language which is understandable...	
<i>Parole (a)(6)</i>	adequate assurance exists that parole boards will not take into account a prisoner's participation...in making decisions regarding parole, & each prisoner is clearly informed in advance that participation...will have no effect on his or her parole...	
<i>Follow-up(a)(7)</i>	where the Board finds there may be a need for follow-up examination or care...after...participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, & for informing participants of this fact.	